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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,709

02/06/2004

Jihad A. Mustapha

SQ1-025

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/773,709	Applicant(s) MUSTAPHA, JIHAD A.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,7,8,10,11,15-17 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,7,8,10,11,15-17 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/07/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/07/2008 has been entered.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 03/07/2008 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

3. Claims 4, 8, 10-11, 15-17, 20-23, 29 are objected to because of the following informalities: The claims begin with "A method" and should rather read --The method--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 3, 4, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Lam** (U.S. Patent No. **5,607,444**).

Lam discloses in fig. 6 a method whereby a stent is placed such that its more expandable proximal end is placed in a primary vessel and the distal portion is placed in a secondary vessel. The stent is expanded by a balloon used to initially expand the proximal portion of the stent with a toroidal portion to form a flange in the primary vessel and fully inflating the balloon to expand the stent to support the secondary vessel with an ovoid distal portion. The toroidal proximal portion of the balloon expands more than the distal portion. The struts 27 are longer than those of the rest of the knitted or braided stent.

6. Claims 3, 4, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Myler** (U.S. Patent No. **5,632,762**).

Myler discloses in fig. 7 and 8 a method whereby a stent is placed such that its more expandable proximal end is placed in a primary vessel and the distal portion is placed in a secondary vessel. The stent is initially expanded by a balloon which is fully inflated and has an ovoid distal portion used to expand the stent to support the

secondary vessel and a rather toroidal proximal portion which expands more than the distal portion and expands the proximal portion of the stent to form a flange in the primary vessel. The struts bent out to form the flange would be longer than the rest of the struts.

7. Claims 3-4, 7-8, 10-11, 15-17, 19-23, and 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by **Vardi, et al.** (U.S. Patent No. **6,210,429**) or Vardi, et al. (U.S. Patent No. 6,325,826).

Both Vardi references disclose in fig. 6 a-g a method whereby a stent is placed such that its more expandable proximal end is placed in a primary vessel and the distal portion is placed in a secondary vessel. The stent is expanded by a balloon which has an ovoid distal portion used to expand the stent to support the secondary vessel and a rather toroidal proximal portion which expands more than the distal portion and expands the proximal portion of the stent to form a flange in the primary vessel (fig. 6f; col. 8, lines 1-4).

Additionally, the same figures show a first step whereby a first stent is placed in an inlet portion and one outlet portion of a bifurcated vessel. The stent is expanded to support these vessel sections. Then a second stent is inserted into the second outlet portion through an aperture in the side wall of the first stent such that it supports the second vessel portion while its proximal end which is more expandable is expanded with a balloon having a more expandable portion in order to cause it to obtain a larger flange-like portion which expands and interlocks inside the first stent around the

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periphery of the aperture. The flanges are struts longer than the struts making up the rest of the stent (each strut can be referred to as extending from one intersection with other struts to the next intersection with another strut). It also appears that in figs. 6d-e when the stent 15 is initially deployed, the distal end of the expandable member is inflated to thereby trap plaque within the stent.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 24-31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lam** (U.S. Patent No. **5,607,444**).

Lam discloses the claimed invention, as mentioned in paragraph 5 above, but does not expressly teach initially inflating the expandable member such that the proximal portion is inflated and the distal portion is not fully inflated, thereby flaring the proximal stent portion, and fully inflating the expandable member to deploy the distal stent portion within the ostial branch. In other words, Lam does not explicitly teach the step of inflating the proximal portion of the expandable member preceding the step of fully inflating the distal portion of the expandable member, as well as inflating a distal end of the distal portion of an expandable member to thereby trap plaque within the stent. However, Lam teaches using various sized and shaped balloon segments to

deploy the ostial stent which may be at different degrees of inflation, and that the flared proximal portion may be expanded before, after, or simultaneously with the distal portion of the stent (col. 7, lines 10-30). It would have been obvious to one of ordinary skill in the art at the time of invention to initially inflate the expandable portion to expand the proximal portion before fully inflating the distal portion in order to ensure proper “capping” of the flared portion for repair of the diseased portion of the bifurcated vessel.

Response to Arguments

10. Applicant's arguments filed 03/07/2008 have been fully considered but they are not persuasive.

11. In regards to claims 3-4, 7-8, 10-11, and 19-23 the applicant generally argues that Lam, Myler, and Vardi do not disclose initially inflating the proximal portion of the balloon, and then fully inflating the balloon whereby the distal portion of the balloon expands to support the secondary vessel. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. The recitation (in claims 3, 7, and 19 in particular) does not clearly state that the proximal portion of the balloon is inflated to deploy the flange portion of the stent before fully inflating the rest of the balloon to deploy the distal portion of the stent.

12. Applicant also argues that Lam fails to disclose a bulbous-shaped balloon. However, “bulbous” may be interpreted as “having any rounded projection or part,” and therefore the examiner asserts that the balloon of Lam (see fig. 6) may be reasonably characterized as “bulbous.”

13. Lastly, applicant argues that the branch stent 15 in Vardi et al. is not expanded by a balloon or expandable member, but rather is initially collapsed by a protective sheath which is withdrawn to expand the self-expanding contacting (flange) portion 18. However, the examiner asserts that while removal of the protective sheath 34 allows the flange portion 18 to initially expand (as in fig. 6d), the flange portion is further expanded by the balloon in fig. 6f until it is fully expanded (col. 8, lines 1-4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731